MIGRATING FROM ROUTINE TO RISK BASED INSPECTION (RBI) -OPTIMIZING THE HUMAN RESOURCES IN POST PANDEMIC.

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Mr. Chairman, distinguished guests, ladies and gentlemen, risk is simply a function of the probability of occurrence of harm and the severity of the harm as per the International Conference on Harmonization (ICH) Q9 definition.

The control of risks in the pharmaceutical industry is largely related to patient safety. The use of the risk tool in a more standardized and comprehensive manner across medicines manufacturing, storage and distribution defines how patient safety can be guaranteed. The robust approach has been the use of quality risk management systems (QRMS).

Compliance with Good Manufacturing Practices (GMP) and Good Distribution Practices (GDP) throughout the medicine product lifecycle, provide assurance that risks are largely controlled and the product is safe. In light of this, the Food and Drugs Authority, Ghana (FDA Ghana) regulates all drugs locally manufactured, imported, exported, distributed, sold or used in Ghana. This is achieved by inspection and licensing of the manufacturing and storage facilities, registration, market surveillance and control, authorization and control of clinical trials, safety monitoring, quality control testing, approval and monitoring

The FDA Ghana's current approach to GMP inspections has been on-site inspections and desktop review of documentation, making use of a waiver system that is risk-based. This system incorporates a Failure Mode and Effect Analysis (FMEA) for each of the identified procedures under each inspection activity.

A risk-based reliance policy is applied alongside a risk-based approach to GMP inspection scheduling. It is worth noting that the FDA Ghana has achieved the WHO Maturity Level 3 and is working hard towards achieving Maturity Level 4 by the end of first Quarter of 2023.

FDA Ghana's inspection waiver policy document considers risk factors such as geographical location of facilities alongside the quality of the existing regulatory systems and the risk-based

inspection scheduling considers risk factors such as product and process risk, the manufacturer's compliance history and past product recall history .

FDA Ghana intends to expand its risk approach to include the prioritization for inspection of manufacturing product lines based on risk especially for facilities seeking market authorisation for more than one product. It also intends to expand the scope of facilities under the on-site inspection waiver policy and explore the possibility of carrying out joint inspections with other NMRAs.

In its bid to improve risk-based approaches to regulation, the FDA Ghana has encountered challenges in establishing memoranda of understanding between NRAs.

The COVID-19 pandemic has compelled government regulatory agencies to consider the adoption of risk-based reliance-policies. Recovering from the crisis – and preparing for future crises – requires a correct understanding of risk mechanism although these systems may have performed effectively in various jurisdictions.

As the world moves from the new normal to normal times, the need for the migration to risk-based inspections cannot be overemphasised.

It is cost effective, supports a smart work environment and offers an efficient human resource management.

Risk based inspections (RBI) usually assume collaborative approach, offer opportunities for industry partners to have useful diverse views of the risk factors and rankings, thus optimizing service delivery.

As we brainstorm on the RBI post-pandemic, the existing approaches such as the use of quality risk management in the pharmaceutical industry and pharmaceutical regulatory environment must be re-assessed.

Mr. Chairman, I will conclude by saying that total migration to Risk-based Inspections will require robust, reliable knowledge sharing systems and assessment mechanisms.

Thank you